

**REMARKS**

The Office Action dated December 16, 2008 has been carefully considered. Accordingly, the present Amendment is believed sufficient to place the present application in condition for allowance. Reconsideration is respectfully requested.

By the present amendment, claims 1 and 24 have been amended to recite that the overall proton concentration is controlled by adding a molecular weight control agent consisting of water, in accordance with the teachings in the specification, for example, at page 18, line 22-page 20, line 2 and the Examples. Claims 1 and 24 have also been amended to include limitations from claims 6 and 17, which are cancelled. It is believed that these changes do not involve any introduction of new matter, whereby entry of the present amendment is in order and is respectfully requested.

Claims 1, 4, 6 and 10-25 were rejected under 35 U.S.C. §103(a) as being unpatentable over Shinoda (US 5,412,067) in view of Howelton (US 5,342,918) and the *Handbook of Thermoplastic Polymers*, Chapter 2, pages 80-94 (HTP). Claims 7-9 were rejected under 35 U.S.C. §103(a) as being obvious and unpatentable over this combination of references and further in view of Early (US 6,437,565). Applicants respectfully traverse these rejections and request reconsideration of the patentability of currently pending claims 1, 4, 7-16 and 18-25.

As defined by claim 1, the invention is directed to a process for producing an aliphatic polyester by subjecting a cyclic ester to bulk ring-opening polymerization. The process comprises providing a cyclic ester purified to the extent that a water content is at most 50 ppm, an  $\alpha$ -hydroxycarboxylic acid content is at most 100 ppm, and linear  $\alpha$ -hydroxycarboxylic acid oligomers content is at most 1000 ppm, and controlling an over all proton concentration in a ring-opening polymerization system by adding a molecular weight control agent consisting of

water to the cyclic ester to control the overall proton concentration in the cyclic ester to be within a range of higher than 0.09 mol% but lower than 2.0 mol%. The overall protein concentration in the cyclic ester is calculated out on the basis of the total amount of hydroxycarboxylic compounds consisting of  $\alpha$ -hydroxycarboxylic acid and the linear  $\alpha$ -hydroxycarboxylic acid oligomer as impurities in the cyclic acid, water contained as impurities in the cyclic ester, and water added to the cyclic ester. The process further comprises subjecting the cyclic ester to ring opening polymerization in a closed state and in the presence of a ring-opening polymerization catalyst, thereby controlling melt viscosity of the resulting aliphatic polyester to have a melt viscosity of 50 to 6000 Pa·s as measured at a temperature of 240°C and a shear rate of 121 sec<sup>-1</sup>. Claim 24 recites a similar process wherein the aliphatic polyester is polyglycolic acid.

It has been found that when an aliphatic polyester such as polyglycolic acid is produced by ring-opening polymerization of a cyclic ester such as glycolide using a high-purity cyclic ester and a molecular weight control agent consisting of water is added to the cyclic ester to control the overall proton concentration in the cyclic ester, the melt viscosity and the molecular weight of the formed polymer can be precisely controlled. It has not previously been known that the melt viscosity and molecular weight of an aliphatic polyester can be controlled by controlling the overall proton concentration in the cyclic ester, particularly to be within a range of higher than 0.09 mol% but lower than 2.0 mol%, with the addition of only water. As demonstrated in the Examples and Comparative Examples in the present specification, the presently claimed process allows the production of aliphatic polyesters having good, precisely controlled melt viscosity, desired molecular weight, and low yellowing.

In the Official Action, the Examiner asserted that Shinoda is “silent about addition of water” to the polymerization system but asserted Howelton teaches addition of water as a polymerization initiator, referring to column 1, line 20 of Howelton.

Applicants submit however that, contrary to the Examiner’s assertion that Shinoda is silent about addition of water, Shinoda specifically leads one of ordinary skill in the art away from a process wherein water is added to the cyclic ester. That is, Shinoda indicates that when the moisture content of the cyclic ester is high, molecular weight control of the polyester is liable to be difficult. Shinoda therefore discloses that water is an impurity (column 2, lines 47-48). Shinoda further discloses that the water content in the cyclic ester is preferably controlled to at most 100 ppm or less and that the moisture can be removed from the cyclic ester compound by known processes such as deairing or heat drying (see Shinoda, column 6, lines 37-52). Thus, not only does Shinoda fail to disclose addition of water to the cyclic ester, Shinoda is not silent about water. Rather, Shinoda teaches that water is undesirable and should be removed. Importantly, since Shinoda considers water as an impurity, it is apparent that a person of ordinary skill in the art would not have found the addition of water obvious in view of Shinoda.

Additionally, claims 1 and 24 recite the step of adding a molecular weight control agent consisting of water to control the proton concentration, followed by polymerization, thereby controlling the melt viscosity of the resulting aliphatic polyester. On the other hand, Shinoda specifically teaches the use of hydroxyl compounds for controlling the molecular weight of polyesters, and particularly uses higher alcohols such as lauryl alcohol. Such hydroxy compounds, and particularly higher alcohols, are excluded in the present processes wherein the molecular weight control agent consists of water.

This is a significant difference between the claimed production processes and the teachings of Shinoda. In this regard, the Examiner's attention is again directed to Comparative Example 3, which uses 1-dodecyl alcohol (lauryl alcohol), preferred for use by Shinoda. As noted previously, the use of 1-dodecyl alcohol provides a resulting aliphatic polyester in which the amount of volatile matter (residual monomer) is high, specifically 15.2, exceeding the upper limit of claim 20. Moreover, as indicated in the present specification, the use of 1-dodecyl alcohol, or other hydroxyl compound, in a production process has significant disadvantages. First, a higher alcohol such as lauryl alcohol/1-dodecyl alcohol is expensive, whereby its use increases production costs. Further, lauryl alcohol/1-dodecyl alcohol is a viscous material and tends to remain in a charging device (for example, a syringe) when charged into a polymerization reaction system, and therefore loss of material in the charging step further increases production costs. When a higher alcohol is used in production on an industrial scale, it can be easily recognized that not only are the production costs for the aliphatic polyester increased in that (1) the amount of alcohol used becomes great, and (2) a tank and a weighing device which are temporarily used for charging the alcohol into a polymerization reactor are enlarged in size, but also (3) safety measures must be taken as the alcohol is typically combustible, (4) cleaning of the apparatus is required after used, and (5) cleaning liquids used in the cleaning of the apparatus must be treated before disposal.

In addition, when a higher alcohol is added to a cyclic ester, the higher alcohol is introduced into the resulting aliphatic polyester polymer structure as the higher alcohol also acts as an initiator, whereby the physical properties of the resulting aliphatic polyester are changed. Further, since the higher alcohol is insufficiently soluble in the cyclic ester, the ring-opening polymerization reaction takes place unevenly, preventing precise control of the molecular weight

and melt viscosity of the resulting polymer, as discussed at page 6, line 17-page 7, line 18 of the present specification. Thus, the processes of the present invention are significantly different from the process of Shinoda.

The Examiner relies on Howelton to resolve the deficiency of Shinoda in failing to teach addition of water to control proton concentration. The Examiner appears to assert that Howelton's teaching of addition of water is applicable to all ring-opening polymerizations to start the polymerization. However, Howelton is directed to carboxyl-terminated polyetheramides produced by capping polyetheramides with cyclic lactams, and the Howelton disclosure relied upon by the Examiner at column 1, line 20 is in reference to nylon production in Howelton's discussion of the prior art, namely:

"It is well known that polyamides such as nylon-5, nylon-6, nylon-8, and nylon-12 have been produced by ring-opening polymerization of appropriate lactams. Nylon-6, also called polycaprolactam, was originated by I. G. Farbenindustrie in 1940. In one preparation technique, the polymerization of  $\epsilon$ -caprolactam (also known as  $\epsilon$ -aminocaprolactam or simply caprolactam), is carried out by adding water to open the ring and then removing water again at elevated temperature, where linear polymer forms. Caprolactam may also be polymerized by ionic chain mechanisms." (see column 1, lines 13-23).

Howelton does not discuss any production process for producing an aliphatic polyester, and the Examiner has not provided any evidence of record that one of ordinary skill in the art would find Howelton's reference to nylon production to be relevant to a process for producing an aliphatic polyester.

Howelton additionally discloses at column 6, lines 12-21 and 42-45 that water may be added to aid in opening the lactam. Again, the Examiner has not provided any evidence of record that one of ordinary skill in the art would find Howelton's reference to lactam opening for

a reaction for capping polyetheramides to be relevant to a process for producing an aliphatic polyester.

Moreover, the Examiner has asserted that both Shinoda and Howelton belong to the same art of polycondensation by a ring-opening mechanism, wherein water can be a catalyst of ring opening polycondensation in both processes and one of ordinary skill in the art could apply the teaching of Howelton in order to modify the process of Shinoda. However, Howelton does not recognize water as a catalyst of ring-opening polymerization as is apparent from the fact that Howelton discloses the use of a heterogeneous or homogeneous acid catalyst such as hypophosphorous acid, phosphoric acid or phenyl phosphoric acid may be employed (column 6, lines 7-8), and then goes on to discuss the use of water to open the lactam. As Howelton does not disclose the use of water as a catalyst, Howelton does not suggest to one of ordinary skill in the art to use water as a catalyst in the polymerization process of Shinoda. Moreover, the process of Shinoda employs a ring-opening polymerization catalyst, and thus has no need for water to be added to initiate ring opening.

Additionally, the Examiner asserted that Shinoda discloses that both catalyst and initiator can be present at column 2, lines 40-45. However, Shinoda merely discloses that in the prior art, even though the catalyst amount, initiator amount, reaction temperature, reaction time and conversion rate are individually controlled, polymers having a constant molecular weight cannot be obtained. In fact, at column 2, lines 11-26, Shinoda concludes that prior art examples using an initiator do not show consistent production of polymers having a desired viscosity/molecular weight. Thus, one of ordinary skill in the art would not be motivated to follow these teachings of Shinoda.

Importantly, Howelton provides no motivation or apparent reasoning for one of ordinary skill in the art to proceed contrary to the teaching of Shinoda that moisture should be removed, and to add water to Shinoda's cyclic ester. Howelton's reference to nylon production provides no such motivation or apparent reasoning. Finally, even if such a modification of the Shinoda process was made and water was added, along with Shinoda's hydroxyl compound, although Applicants submit that such a modification is not obvious in view of the prior art, the presently claimed processes do not result, as the processes of claims 1 and 24 recite adding a molecular weight control agent consisting of water to control the overall proton concentration. To the contrary, Shinoda requires the hydroxyl compound molecular weight modifier.

The deficiencies of Shinoda and Howelton are not resolved by HTP. The ring-opening polymerization of the cyclic ester as recited in claims 1 and 24 is performed in a closed state so that the overall proton concentration in the cyclic ester is prevented from changing by mixing of water (moisture) in an external atmosphere. In order to precisely control the melt viscosity of the aliphatic polyester according to the process of the present invention, it is necessary to strictly control the polymerization reaction system in such a manner that the overall proton concentration, including the added water, is retained to a predetermined value. In contrast, HTP only states a general theory as to ring-opening polymerization and does not suggest the fact that the overall proton concentration, including the amount of added water, in the cyclic ester should be precisely controlled by conducting the polymerization reaction system in a closed state.

Additionally, at pages 90-94 referred to by the Examiner, HTP describes ring-opening polymerizations for polycaprolactone and polylactide production. Importantly, on page 94, HTP discloses that the cyclic dimer will contain neither water nor linear oligomers for production of polylactide. Thus, HTP, like Shinoda, teaches away from water addition. Further, while HTP

indicates that the lack of volatile byproducts eliminates the requirement for a vacuum, Applicants find no teaching that the reaction should be conducted in a closed system as presently claimed, and Applicants particularly find no teaching or suggestion of the specific process steps and apparatus as recited in the present claims.

Moreover, as Howelton discloses both the addition and removal of water in the lactam-opening step, Howelton teaches away from the use of a closed system, whereby any teaching of HTP suggesting the use of a closed system is not properly combinable with Howelton.

Early similarly fails to resolve the deficiencies of Shinoda and Howelton and specifically fails to teach or suggest addition of water or any relation between the overall proton concentration in the cyclic ester and the melt viscosity of the aliphatic polyester. In view of this deficiency in the teachings of Early, Shinoda, Howelton, and HTP, the combinations of these references as asserted by the Examiner provide no motivation or apparent reasoning for one of ordinary skill in the art to add a molecular weight control agent consisting of water to the cyclic ester of Shinoda on the basis of a relational expression between a predetermined overall protein concentration in the cyclic ester and a melt viscosity of the aliphatic polyester, as recited in claims 7-9.

Although Applicants submit that the Examiner has not established a prima facie case of obviousness based on Shinoda, even in view of Howelton, HTP and Early, the showings set forth in the Examples and Comparative Examples of the present application rebut any prima facie case of obviousness established by the Examiner. That is, the results of Examples 1 to 4 in Table 1 and 5 to 8 in Table 2 of the present specification, according to the process of the present invention, show ring-opening polyglycolic acids having a relatively high melt viscosity can be obtained by adding water as claimed. In addition, Examples 7 and 8 particularly show a

tendency to remarkably improve the yellowness index (YI), even in a region wherein the melt viscosity and weight average molecular weight are relatively low, when water is used as the molecular weight control agent. A ring-opening polymer low in both melt viscosity and yellowness index (YI) is desirable for use as a polymer for injection molding. Finally, Comparative Example 3 in Table 1 of the present specification shows that the yellowness index (YI) of the ring-opening polymer formed when lauryl alcohol is added as the molecular weight control agent is high (15.1) compared with that of the ring-opening polymers (Examples 6 and 7 in Table 2) each having a similar weight average molecular weight.

When an applicant demonstrates substantially improved results and states that the results were unexpected, this should suffice to establish unexpected results in the absence of evidence to the contrary, *In re Soni*, 34 U.S.P.Q. 2d 1684, 1688 (Fed. Cir. 1995). The Examples and Comparative Examples set forth in the present specification demonstrate substantially improved results provided by the process according to the present invention. Applicants have stated that the results were unexpected, and the Examiner has not provided any evidence to the contrary. Thus, Applicants have rebutted any *prima facie* case of obviousness based on Shinoda.

The Examiner's effort to establish obviousness by showing that the addition of water may be found somewhere in the prior art, namely in the polyamide production of Howelton, is unavailing; in determining obviousness, the inquiry is not whether each element existed in the prior art, but whether the prior art made obvious the invention as a whole for which patentability is claimed. *Grain Processing v. American Maize*, 5 U.S.P.Q. 2d 1788, 1793 (Fed. Cir. 1988). More recently, the Supreme Court has stated that in determining patentability under 35 U.S.C. §103, it is necessary to determine whether there was an apparent reason to combine the known elements in the fashion of the claims at issue, *KSR International Co. v. Teleflex, Inc.*, 550 US

398, 418 (2007). Not only does Howelton fail to teach the addition of water to a cyclic ester, Howelton fails to provide any apparent reason which would cause one of ordinary skill in the art to omit the use of the hydroxyl compound of Shinoda and to use a molecular weight control agent consisting of water, an impurity according to the teachings of Shinoda. Accordingly, the cited prior art does not make the present invention as a whole obvious.

It is therefore submitted that the processes defined by present claims 1, 4 and 7-16 and 18-25 are nonobvious over and patentably distinguishable from the cited combination of Shinoda, Howelton, and HTP, or these references in further combination with Early, whereby the rejections under 35 U.S.C. §103 have been overcome. Reconsideration is respectfully requested.

Claims 1, 4, 6 and 10-25 were provisionally rejected on the ground of nonstatutory obviousness type doubling patenting as being unpatentable over claims 1 and 4-12 of copending Application Serial No. 10/575,468 in view of Shinoda and Howelton. This rejection is traversed. However, to expedite prosecution, submitted herewith is a Terminal Disclaimer disclaiming the terminal portion of any patent issuing on the present application which would extend beyond the expiration date of any patent issuing on copending application Serial No. 10/575,468. The filing of a terminal disclaimer simply serves the statutory function of removing the rejection of double patenting, and raises neither presumption nor estoppel on the merits of the rejection, *Quad Environmental Technologies v. Union Sanitary District*, 946 F.2d 870 (Fed. Cir. 1991). Thus, the rejection is overcome.

Finally, Applicants advise that the presently claimed subject matter and that of copending Application Serial No. 10/575,468 were commonly owned at the time the present invention was made.

It is believed that the above represents a complete response to the Official Action and places the present application in condition for allowance. Reconsideration and an early allowance are requested.

Please charge any fees required in connection with the present communication, or credit any overpayment, to Deposit Account No. 503915.

Respectfully submitted,

/Holly D. Kozlowski/

Holly D. Kozlowski, Reg. No. 30,468  
Porter, Wright, Morris & Arthur LLP  
250 East Fifth Street, Suite 2200  
Cincinnati, Ohio 45202  
(513) 369-4224